

REMARKS

Claims 1-4, and 12-13 are currently pending in the application. Claims 5-11 and 14-22 are canceled without prejudice for being drawn to a non-elected group or species. Applicants preserve their right to pursue these claims in this or a related application.

Claim 12 has been amended to depend from claim 1 and to include the phrase "at least". Support for the amendment can be found in the specification as filed, *e.g.*, page 13, lines 24-25. No new matter is added.

The following applications are currently co-pending with the instant application: USSN 09/953,807, filed September 17, 2001; USSN 09/953,814, filed September 17, 2001; and USSN 10/052,131, filed January 17, 2002.

Rejection Under 35 U.S.C. §112, First Paragraph

Enablement

Claims 1-4, 7, and 12-13 stand rejected under 35 USC §112, first paragraph. Claim 7 is canceled herein. Thus, the rejection is moot with respect to this claim. According to the Examiner, the specification, while enabling for a crystal structure of the *T. thermophilus* 30S subunit, does not provide enablement for any 30S subunit. Applicants respectfully traverse the rejection as applied to the claims as amended.

The Examiner's premise that Applicants do not disclose by guidance or working examples methods for making crystals for different species based on the property of structural conservation of the ribosome is unfounded. As previously indicated, page 11, lines 11-29 of the instant specification clearly indicates that the structures provided therein are useful to solve structures of 30S subunits derived from other prokaryotic species precisely because of the conservation of structure of the ribosome among prokaryotic species. Furthermore, Applicants provide ample disclosure on the production of crystals of (*see, e.g.*, specification at page 12, line 24, through page 13, line 27, and page 22, line 29 through page 23, line 6). Although crystals may be grown by any suitable means known to those skilled in the art, Applicants teach that

crystals of the 30S *T. thermophilus* were obtained by methods substantially similar to Trakhanov et al., FEBBS Lett. 220, 319-322 (1987). Specification, page 3, lines 1-10; and page 22 line 29 through page 23, line 6.

Moreover, one of ordinary skill in the art as of the earliest effective filing date of the instant application could have routinely cultured various prokaryotic organisms and isolated the 30S subunit of the ribosome. The ribosomal subunits are notoriously abundant in living cells due to their role in protein synthesis. Furthermore, because the structural conservation of the 30S ribosome subunit among prokaryotic species is high, so is the predictability that the 30S subunits from various species can be crystallized using the same methods disclosed in the instant application. Applicants believe that these facts, taken together, moot the Examiner's concerns regarding growth conditions, metabolic properties, and the protein-surrounding environment of other prokaryotic species as they relate to crystallography.

Additionally, Applicants respectfully assert that the Examiner's reliance on Drenth and Service (New Focus article) to show lack of enablement is misplaced. First, the Drenth excerpt is cited for the proposition that protein crystallization is a "trial and error method, and the results are usually unpredictable." Drenth was published in 1994 - six full years before the earliest effective filing date of the instant application. Thus, given the nature of rapid advances in science what was once considered unpredictable may now be predictable. *See Enzo Biochem, Inc. v. Calgene, Inc.* 188 F.3d 1362, 52 USPQ2d 1129, 1138 n.10 (Fed Cir. 1999). Second, the Service article speaks only to crystallography as it relates to large-scale protein mapping of thousands of various individual proteins. The instant application is not concerned with such methods, but rather with the crystallography of structurally conserved ribosomal 30S subunits derived from prokaryotic sources.

Furthermore, Applicants submit that the structural conservation of the ribosomal 30S subunit is so great among prokaryotic species that a single embodiment provides broad enablement in the sense that 30S subunits can be obtained from other prokaryotic species and crystallized without difficulty. Thus, there is a high degree of predictability for forming crystals of 30S subunits isolated from other prokaryotic species, not a low degree of predictability as the Examiner suggests. While the instant application is assigned to an art area historically labeled as

“unpredictable,” that factor alone is not determinative of whether Applicants can generically claim more than the particular species disclosed in their specification. *See In re Vaeck* 947 F.2d 488, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). Accordingly, Applicants assert that due to the high degree of structural conservation of the 30S subunit among prokaryotic species, the instant claims should be given a deference similar to those of a mechanical or electrical nature when determining enablement. *See In re Fisher*, 427 F.2d 833, 166 USPQ 18, 24, (CCPA 1970); *see also Gould v. Mossinghoff*, 711 F.2d 396, 219 USPQ 393, 396 (DC Cir. 1983).

Finally, while Applicants recognize that the instant claims must be patentable as of their own right, Applicants contend that similar claims allowed by the Patent Office can serve as evidence of what is regarded as patentable subject matter, particularly in similar applications. *See In re Schecter*, 205 F.2d 185, 98 USPQ 144, 150 (C.C.P.A. 1953). Notably, claims 1-4 and 12-13 of the present application mirror claims 1-3 of Applicants’ U.S. Patent 6,925,394 B2, issued August 2, 2005 (previously copending Application Serial No. 09/904,779).

In the present application, claims 1-4 are directed to crystals of a 30S ribosomal subunit bound to certain defined antibiotics, wherein the crystal has a defined tetragonal space group and unit cell dimensions. Claims 1-2 of the ‘394 patent are analogous, except that claims 1-4 of the present invention also recite a bound antibiotic. It is respectfully submitted that claims 1-4 of the present application, which recite this additional limitation, should also be allowed.

Also in the present application, claim 13 is directed to crystals of a 30S ribosomal subunit having a structure defined by the co-ordinates of tables 1-4. This claim is analogous to claim 3 of the ‘394 patent, which is also defined by co-ordinates. It is respectfully submitted that claim 13 of the present application should also be allowed.

Written Description

Claim 12 stands rejected for failing to comply with the written description requirement.

According to the Examiner (Advisory Action of June 7, 2005), Applicant’s argument is not persuasive with respect to claim 12, because the pointed to specification is directed to the

crystal obtained from a *Thermus thermophilus* 30S subunit, bound to an antibiotic from a list of antibiotics, **having a specified space group**. While, the claim is directed to a generic prokaryotic 30S ribosomal subunit, bound to an antibiotic from a list of antibiotics **without specifying any space groups**. [Emphasis added.]

Applicants respectfully submit that in view of the amendment to claim 12, to make it depend from and include the space groups recited in claim 1, that the rejection has been overcome. Additionally, as suggested by the Examiner in the Office Action of November 17, 2004 (sentence bridging pages 2-3), Applicants have further amended claim 12 to recite a prokaryotic 30S ribosomal subunit crystal having a resolution of at least about 3 Å.

In view of the foregoing arguments and amendments, Applicants respectfully request allowance of claims 1-4, and 12-13.

Obviousness-Type Double Patenting


Claims 1-4, 7, and 12-13 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-4 of co-pending Application Serial No. 09/904,779 (now U.S. Patent No. 6,925,394 B2). Claim 7 is canceled herein. Thus, the rejection is moot with respect to this claim.

Upon indication of allowable subject matter in the instant application, a terminal disclaimer will be filed. Allowance of claims 1-4 and 12-13 are earnestly requested.

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

The Commissioner is authorized to charge any additional fees that may be due, or to credit any overpayment, to Deposit Account No. 50-0311, Reference 26505-511.

Respectfully submitted,

A handwritten signature in cursive script, reading "Charles E. Bell", written over a horizontal line.

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